REMARKS

Claims 1-18 and 31 are pending in the present application. The following rejections remaining at issue and are set forth by number in the order in which they are addressed:

1. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 in view of Cook et al. U.S. Patent No. 5,760,082; and
2. Claims 1-18 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594); and
3. Claims 4, 7, 18 are rejected under 35 U.S.C. §112, second paragraph, as indefinite.

Claims 4, 7, and 13 have been amended. Support for new Claim 31 is found at page 22 of the specification, among other places. Applicants believe that the amendments and remarks present herein traverse all of the Examiner's remaining rejections.

1. The Double Patenting Rejection Is Improper

Applicants contend that the double patenting rejection is not proper for the reasons stated in the prior Responses. Nevertheless, Applicants herein offer to submit a Terminal Disclaimer over the U.S. 6,015,833 upon the Examiner's indication of patentable subject matter in the instant application.

2. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

Claims 1-18 remain rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594). Applicants must again respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b)

provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue.[1] In addressing this rejection, Applicants focus on the independent claims since the non-obviousness of independent claims necessarily leads to the non-obviousness of the claims dependent thereon.[2]

A. No Motivation To Combine The References

In their previous Response, Applicants submitted extensive arguments explaining why there is no motivation to combine the references cited by the Examiner. Applicants respectfully submit that the Examiner has failed to successfully rebut these arguments. With respect to motivation to combine, the Examiner begins by stating that "Initially, it is noted that Cook employed alchoholate catalyst for preparing the conjugated linoleic acid. (ethylene glycol is a dihydric alcohol)." (Office Action, p. 6). Applicants respecfully note that this argument is scientifically flawed. Cook did not use an alcoholate catalyst as defined in the present invention. Indeed, the specification provides the following definition for "alcoholate catalyst" at page 8:

> As used herein, the term "alcoholate catalyst" refers to alkali metal compounds of any monohydric alcohol, including, but not limited to, potassium methylate and potassium ethylate.

In contrast, Cook utilized either NaOH or KOH as a catalyst. Ethylene glycol is the solvent in which the catalyst is employed. Thus, the Examiner's rebuttal is flawed.

Next, the Examiner repeats his argument that the "Baltes reference does not expressly [sic] limited to produce CLA for coating" and then provides citations from Baltes. (Office

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[1] *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

[2] §MPEP 2143.03.

Action, p. 6-7). However, the Examiner has again failed to specifically consider the content of the Declaration of Mr. Asgeir Sæbo. As detailed in the Sæbo Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption. Thus, the Examiner's attempt to claim that the compositions of Baltes could be used in a food product is misguided. In fact, the Baltes reference indicates that the uses the products are suited for are industrial in nature. In particular, Baltes et al. describe methods for producing conjugated linoleic acids described as being "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., *col.* 9, *ll.* 47-60). As such, the Baltes reference is directed to the production of substitutes for tung oil that are not suitable for consumption. The tung oil substitutes described in Baltes et al., are intended for industrial uses such as for drying oils, varnishes, and lacquers. Consequently, Baltes et al., describes methods for producing toxic oil substitutes for non toxic oils (tung oil). Nothing in the Baltes et al. reference teaches or suggest the desirability--or even applicability--of using the methods disclosed therein to produce food products.

It should be noted that the failure of the Examiner to properly consider the Sæbo Declaration is grounds for reversal by The Baord of Patents Appeals and Interferences should this case be appealed. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

> **Office personnel should consider all rebuttal arguments and evidence presented by applicants**. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id. See also In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).
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> A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745

F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.[3]

Additionally, the Courts have held as follows:

> When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.[4]

Furthermore:

> If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.[5]

Accordingly, even if the Examiner had established a *prima facie* of obviousness in the preceding office action (and Applicants contend that he did not), the Examiner must respond to Applicants arguments.

For the reasons stated above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore respectfully request that this rejection be withdrawn.

B. References Do Not Teach All Of The Elements Of The Claims

The claims to require that the CLA compositions are treated so that less than 5 ppm volatile organic materials are present. The cited prior art references do not teach or suggest these treatment methods or alternative treatment methods for producing the food-grade quality CLA of the present invention. For example, as stated in paragraph 5 of the previously

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[3] MPEP §§2144.08; emphasis added).

[4] *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

[5] *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

submitted Sæbo Declaration, the starting materials used by Baltes produced compositions that were unstable and would have high levels of breakdown products.

These arguments, which presented in the previous Response, have been ignored by the Examiner. Instead of directly addressing these arguments, the Examiner states that:

> As stated above, Cook teaches a step to remove volatile components in the CLA composition and keep the composition from oxidation. It would be obvious for one of ordinary skill in the art to keep the level of volatile organic materials low so that the CLA composition would be suitable for food product. (Office Action, p. 7.)

Instead of citing some teaching in the reference of low VOC content, the Examiner **speculates** that the VOC content is low. This speculation cannot substitute for an actual or inherent teaching of the claimed element. Indeed, the Examiner is evidently applying a flawed inherency analysis. As the Federal Circuit has held in *Continental Can*:

> To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Continental Can Company USA, Inc., v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) (emphasis added) (holding no anticipation due to inherency). Thus, argued gaps in a reference must be filled by evidence that clearly shows the descriptive matter is necessarily present. This is a far more stringent standard than the standard urged by the Examiner. Indeed, inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269 (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).

In the present case, the Examiner is relying on possibilities. The low VOC element is not **necessarily** present in the cited references. Accordingly, the cited references, alone or combined, do not teach the low VOC element. The Examiner has failed to establish a *prima facie* case of obviousness. Thus, the Applicants respectfully request that the claims be passed to allowance.

C. The Cited References Do Not Recognize the Problem Solved By Applicants

The cited references fail to appreciate the actual causes of oxidation in CLA compositions (i.e., the problem) and thus do not teach the solutions taught by the Applicants.

In particular, Applicants teach in the specification that the CLA oxidation problem is likely caused by metal ion contamination in the starting material. Applicants solved this problem by using a combination of methods, including, but not limited to addition of metal oxidant chelators and the removal of pro-oxidants by methods such as distillation and treatment with adsorbing agents. (Specification, *p.* 22-23). As demonstrated in the specification, the methods invented by the Applicants' were **necessary** to prevent the oxidation of CLA into the typical CLA oxidant compounds that affect the smell and taste compositions (*e.g.*, food stuffs) containing CLA. It is well settled in patent law that "[i]t should not be necessary . . . to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." (*In re Sponnable*, 405 F.2d 578, 585 (C.C.P.A. 1969); *In re Kosei Nomiya et al.*, 509 F.2d 566, 571 (C.C.P.A. 1975)).

As it stands, none of the cited references teach the removal of pro-oxidants by methods such as distillation and treatment with adsorbing agents and none of the cited references teach compositions comprising conjugated linoleic acid moieties that contain less than 100 ppm volatile organic compounds as are presently being recited. Accordingly, the claims, which are directed to products with low levels of VOC, are not obvious over the cited references.

3. The Claims are Definite

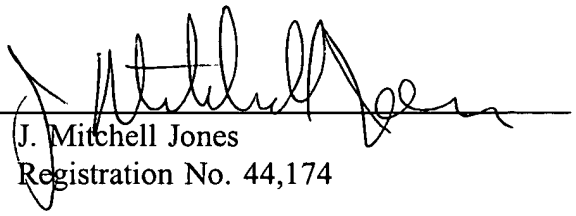
Claims 4, 7, 18 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. Applicants believe the amendments to these claims obviate the rejections.

CONCLUSION

All grounds of rejection and objection of the Final Office Action of January 22, 2003 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview

would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: April 22, 2003



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APPENDIX 1

Marked-up version of the rewritten, added, and/or cancelled claims pursuant to 37 C.F.R. §1.121(c)(1)(ii)

4. (Amended Three Times) The method of Claim 1, wherein step (c) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step ([b]d) to produce said food product.

7. (Amended Three Times) A method for producing a food product containing conjugated linoleic acid comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid; [and]

d) treating said conjugated linoleic acid [esters] under conditions such that the volatile organic compound content of said conjugated linoleic acid [esters] is less than 5 ppm; and

e) combining said foodstuff with said conjugated linoleic acid [esters] from step ([c]d) to produce a food product.

13. (Amended Three Times) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst, and

iii) a foodstuff; and

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and

d) treating said triglycerides containing conjugated linoleic acid moieties under conditions such that the volatile organic compound content of said triglycerides containing conjugated linoleic acid moieties is less than 5 ppm;

e) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step ([c]d) to produce a food product.

31. (New) A method for producing a food product containing conjugated linoleic acid esters comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm after storage;

d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

APPENDIX 2
Clean Version Of The Entire Set Of Pending Claims

1. (Amended Twice) A method for producing a food product containing conjugated linoleic acid esters comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm;

d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

2. The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

3. (Amended once) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

4. (Amended Three Times) The method of Claim 1, wherein step (c) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (d) to produce said food product.

5. (Amended Once) The method of Claim 4, wherein said antioxidant is selected from the group consisting of α-tocopherol, β-tocopherol, lecithin, ascorbylpalmitate, and BHT.

6. (Amended Twice) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

7. (Amended Three Times) A method for producing a food product containing conjugated linoleic acid comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid;

d) treating said conjugated linoleic acid under conditions such that the volatile organic compound content of said conjugated linoleic acid is less than 5 ppm; and

e) combining said foodstuff with said conjugated linoleic acid from step (d) to produce a food product.

8. The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

9. (Amended once) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

10. (Amended Twice) The method of Claim 7, wherein step (d) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

11. (Amended Once) The method of Claim 10, wherein said antioxidant is selected from the group consisting of α-tocopherol, β-tocopherol, lecithin, ascorbylpalmitate, and BHT.

12. (Amended Twice) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

13. (Amended Three Times) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst, and

iii) a foodstuff; and

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and

d) treating said triglycerides containing conjugated linoleic acid moieties under conditions such that the volatile organic compound content of said triglycerides containing conjugated linoleic acid moieties is less than 5 ppm;

e) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step (d) to produce a food product.

14. The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

15. (Amended once) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

16. (Amended Twice) The method of Claim 13, wherein step (d) further comprises treating said triglycerides containing conjugated linoleic acid moieties with an adsorbing agent, providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.

17. (Amended Once) The method of Claim 16, wherein said antioxidant is selected from the group consisting of α-tocopherol, β-tocopherol, lecithin, ascorbylpalmitate, and BHT.

18. (Amended Twice) The food product produced according to the method of Claim 13 , further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

31. (New) A method for producing a food product containing conjugated linoleic acid esters comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm after storage;

d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.